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10/731,302

12/09/2003

William F. Weitzel

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09/12/2006

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EXAMINER

JAWORSKI, FRANCIS J

ART UNIT

PAPER NUMBER

3768

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/731,302

Applicant(s)

WEITZEL ET AL.

Examiner

Jaworski Francis J.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 - 48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10 - 16, 34 - 40 is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-9, 17-19, 22-28, 31-33, 41-43, and 46 - 48 is/are rejected.
- 7) ☒ Claim(s) 5, 6, 20, 21, 29, 30, 44 and 45 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 4, 7 – 9, 17 – 19, 22 – 28, 31 – 33, 41 – 43, 46 - 48 are rejected under 35 U.S.C. 102(b) as being anticipated by de Korte et al (Phys. Med. Biol. 45(2000) pp.1465 – 1475, newly of record).

De Korte proposes both in vivo and in vitro elastographic strain imaging of the layers within the arterial wall, where in the in vitro case an altering force is applied by the researcher (In the in-vivo case measurements are taken at two near-diastolic pressure points in the cardiac cycle without an altering force applied and therefore there is no anticipatory reading however see below).

In the former in vitro case which is detailed in Section 3 and Figure 1 of that article, there is described a method of measuring local arterial strain for an arterial wall which deforms in response to the transmural force of physiologic pressure, comprising

altering the transmural force from 80 to 100 mmHg,

measuring changes in position at locations within the arterial wall from these altered forces in the physiologic pressure range by using cross-correlation function peaks, and

determining a strain value and expressing it as an imaged color based on the measured amount of local position change. (Claim 1)

The strain value is intrinsically non-linear in relation to the hardness variation of atheromatous components.(claim 2).

The imaging is non-invasive because the artery specimen isn't inside a biological organism anymore. (claim 3).

Since two applied pressure values are used, the lesser or 80mm Hg may be regarded as a reduction with respect to the greater 100mm Hg value. (Claims 4,7).

Since claim 8 merely restates the intrinsic nature of arterial walls, it is grouped here.

Rejection of claims 17-19 and 22 - 28 parallels the arguments supra, and with regards to the system for carrying out the method.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 – 2 , 4, 7-9, 17-19, 22 – 28, 31 – 33, 41 – 43, 46 - 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Korte et al. In the in vivo case practiced on coronary arteries of patients, two near-diastolic points in the heart's pressure wave are the measurement points at greater and reduced transmural pressure. While de Korte et al elected to not use the IVUS catheter balloon to apply force in vivo (a conclusion drawn from page 1469, bottom and page 1473 para next-to-last, since de Korte et al elsewhere in Section 2.3, end-sentence state that IVUS balloon pressure application is a known equivalent to native physiologic pressure use it would then have been obvious to use the applied balloon pressure albeit this is a less-favored approach in a cardiac patient exhibiting symptoms in that particular study.

#### ***Allowable Subject Matter***

Claims 5 – 6, 20 – 21, 29 – 30, 44 - 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 10 – 16, 34 - 40 are allowed.


**Response to Arguments**

Whereas the Examiner agrees with the applicants' that the prior-applied references pertained to measurement of properties (compliance, diameter, wall thickness) of the vessel as a whole, the discovery of de Korte et al extends the transmural applied force concept to measurement of local properties within the wall e.g. by production of an elastographic image thereof, albeit there is no suggestion to apply external pressure to the artery and/or alter mean pressure under this regime. . Therefore at least some of the presented claims remain rejected on this new rejection basis.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

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Francis J. Jaworski  
Primary Examiner